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| APPLICATION NO.  | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-----------------|----------------------|---------------------|------------------|
| 10/629,883   | 07/29/2003      | Miroslav Colic       | 4904-3DIV           | 5574             |
|  | 7590 09/29/2005 |                      | EXAMINER            |                  |
| Lance J. Lieberman, Esq.<br>Cohen, Pontani, Lieberman & Pavane<br>Suite 1210<br>551 Fifth Avenue<br>New York, NY 10176 |                 |                      | PAK, JOHN D         |                  |
|  |                 |                      | ART UNIT            | PAPER NUMBER     |
|  |                 |                      | 1616                |                  |
| DATE MAILED: 09/29/2005  |                 |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/629,883 | <b>Applicant(s)</b><br>COLIC, MIROSLAV |  |
|                              | <b>Examiner</b><br>JOHN PAK          | <b>Art Unit</b><br>1616                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 16 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

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Claim 16 is pending in this application.

Applicant is advised that claim 16, line 4 should be amended to correct the grammar in the phrase, "by electrolyzing water in a chamber [ ] have a cathode compartment ...."

The following is a quotation of the first paragraph of 35 USC 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 16 is rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The basis for this ground of rejection pertains to three issues:

(1) except for the specific "cage-like compound[s]" set forth in the specification (see from page 17, line 19 to page 18, line 10), one skilled in the art would not be able to arrive at other such cage-like compounds *to produce encaged atomic hydrogen* without undue experimentation;

(2) the feature "redox potential of said cathode water is reduced to no more than 700 mv and the pH of said cathode water becomes about 11" cannot be obtained by one skilled in the art without undue experimentation; and

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(3) the water to be electrolyzed is not specified – this would appear to be critical since pure water per se (without any additive electrolytes) would not have sufficient conductance to provide the feature described in part (2), supra.

The claimed invention is directed to a method of producing an antioxidant action in the body of a patient, comprising administering **encaged atomic hydrogen**, which is produced by electrolyzing water until the redox potential of cathode water in the cathode compartment is “reduced to no more than 700 mv and the pH of said cathode water becomes about 11” and adding a cage-like compound (broadly claimed) to said cathode compartment during electrolysis.

The nature of the invention thus involves, inter alia, producing encaged atomic hydrogen. However, it must be recognized that atomic hydrogen is an extremely reactive species – applicant acknowledges in the specification that it is the second most powerful reducing agent known (page 9, line 10).

Moreover, at the cathode compartment, the electrolyzed water would be expected to have a redox potential that is less than pre-electrolyzed starting water. Since pH of about 11 indicates significant electrolysis, the claimed 700 mv upper limit (much higher than tap water) is a redox potential that seems incongruous with cathodic water after significant electrolysis, particularly for cathodic water that generates the reductive atomic hydrogen species.

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Applicant's own specification seems supportive of the Examiner's view as **negative** 700 mv is disclosed therein (page 14, lines 11-12).

Further, it would appear from the 700 mv redox potential and pH 11 that such significant electrolysis could not occur from the use of non-specified water since pure water per se would not have sufficient conductance to provide such degree of electrolysis. Indeed, applicant himself adds 100 mg of potassium chloride to 500 ml of cathode water "to enhance the conductivity of water" (specification page 14, line 5). It would appear the broad "water" in applicant's claim is not sufficiently enabled, because only water with sufficient electrolytes such as 100 mg potassium chloride/500 ml would provide effective conductance for sufficient electrolysis.

The state of the art is established by applicant's own specification (page 11, line 18 to page 12, line 10). Applicant acknowledges that known techniques for stabilizing atomic hydrogen involve specific parameters such as very low temperatures, very specific substrates, and toxicity (id.). HCAPLUS abstract 2001:641119 is cited to show that even in the year 2001, the skilled artisans in this art admit to "a guess" as to conditions favorable for entrapping atomic hydrogen. U.S. Patent No. 6,730,211 is cited to establish that the state of the art, which would have led to an expectation that the electrolyzed water in the cathode

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compartment would be lower in redox potential (i.e. lower than the 700 mv claimed by applicant). See column 6, lines 63-67. U.S. Patent No. 5,736,027 is further cited to establish that electrolyzed water in the cathode compartment would be expected to have a redox potential that is much lower than 700 mv (see the Table on column 3, solutions designated as A-1 to A-11). The above two patents are also cited to establish that the prior art electrolysis utilizes water (or "service water") that contains electrolytes. See in Patent No. 6,730,211, column 3, lines 63-67; in Patent No. 5,736,027, column 2, lines 6-15.

The level of one of ordinary skill in this art is quite high due to the extremely challenging task of entrapping or encaging one of the most reactive chemical species. The level of unpredictability in the art is also high due to the difficulty involved in entrapping or encaging one of the most reactive chemical species, especially for final in vivo use without toxicity.

The specification provides insufficient guidance or direction to (i) arrive at additional, unspecified "cage-like" compounds, and (ii) arrive at cathode water with redox potential of 700 mv (or less) and pH of about 11. Except for the cage-like compounds disclosed in the specification (page 17, line 18 to page 18, line 10), it is unclear how other compounds, such as organic compounds with myriad functional groups that could be reduced, would interact with atomic hydrogen –

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e.g., would it be reduced by the second most powerful reducing agent or would it encage such a powerful reducing agent?

As for working examples found in the specification, vitamin B12 is used as the cage-like compound in an electrolytic process with water that contains 100 mg KCl in 500 ml cathode water (pages 14-15; see also pages 20-21). Applicant does not objectively demonstrate the structure or existence of "encaged atomic hydrogen" through analytical data, but rather, attempts to show the same through its antioxidant activity.

In summary, the upper limit of 700 mv for redox potential of electrolyzed cathode water at pH 11 appears incongruous with significant electrolysis (i.e. the redox potential is too high), and the unspecified water in the claim, which includes pure water, would not be expected to produce the aforementioned redox potential and pH, as it lacks sufficient conductivity. Couple these factors with the fact that the second most powerful reducing agent, atomic hydrogen, is expected to be "encaged" by "cage-like" compounds (i.e. not reduced by the atomic hydrogen), which compounds are claimed without any specificity. Except for those cage-like compounds that applicant specifically describes in the specification, in water that contains sufficient electrolytes to be sufficiently conductive, wherein electrolyzed cathode water has a redox potential in the

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negative mv range or close to zero mv, one skilled in the art would have to resort to undue experimentation to make the “encaged atomic hydrogen” as required by the claims.

For these reasons, claim 16 is determined to lack adequate enabling support.

Claim 16 is rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 16 specifies the redox potential of the electrolyzed cathode water as “reduced to no more than 700 mv.”

However, the specification provides somewhat confusing or conflicting disclosures as to the redox potential. For a process involving electrolysis, “at least - 700 mv” is disclosed (page 14, lines 11-12). For a process involving photogeneration, redox potential of “lower than -700 mv” is disclosed (page 15, line 12).

Therefore, it can be plainly seen that **positive** 700 mv was not disclosed in the originally filed disclosure, not even as an upper limit. The only disclosure



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as to redox potential centers around **negative** 700 mv. Whether or not it is "at least -700 mv" or "lower than -700 mv," which have two different meanings, one skilled in the art would nonetheless not understand such disclosures as conveying an upper limit of positive 700 mv.

Therefore, the feature in claim 16, which specifies the redox potential of the electrolyzed cathode water as "reduced to no more than 700 mv" must be determined as lacking sufficient descriptive support from the originally filed disclosure.

For these reasons, the sole pending claim, claim 16, must be refused at this time.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machines is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner John Pak whose telephone number is **(571)272-0620**. The Examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM. If attempts to reach the Examiner by telephone

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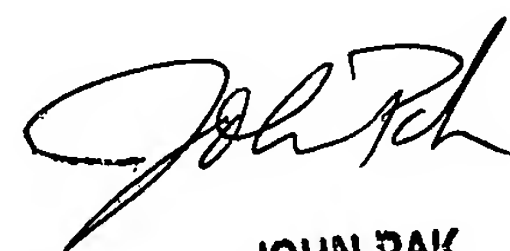
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are unsuccessful, the Examiner's SPE, Mr. Gary Kunz, can be reached on **(571)272-0887**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is **(571) 272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have a question on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
JOHN PAK  
PRIMARY EXAMINER  
GROUP 1600